PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Weiner, R. L. Serial No.: 09/577,258

Filed: May 22, 2000 Docket: P-8769

Title: PERIPHERAL NERVE STIMULATION METHOD

Assistant Commissioner for Patents
Special Programs Office
DAC for Patents
Washington, D.C. 20231

AFFIDAVIT
OF
RICHARD L. WEINER

Dear Sir:

1. I received a B.A. Degree in Bacteriology in 1970 from the University of California, Los Angeles in Los Angeles, California and a M.D. degree from the Medical College of Wisconsin in Milwaukee, Wisconsin in 1975.

2. From 1975 to 1976, I was an Intern, Straight Surgery, Los Angeles County at the University of Southern California Medical Center in Los Angeles, California.

3. From 1976 to 1977, I was a Resident, Neurology, at New York University Medical Center, New York, New York.

4. From 1977 to 1980, I was a Resident, Neurosurgery, at New York University Medical Center, New York, New York.

5. From July 1980 to December 1980, I was an Instructor, Department of Neurosurgery, at New York University Medical Center, New York, New York.

6. From January 1981 to July 1987, I was Assistant Professor of Surgery (Neurosurgery) at The University of Texas Medical Branch, Galveston, Texas.

7. From January 1981 to July 1987, I was the Director, Non-Invasive Diagnostic Vascular Laboratory, Division of Neurosurgery, The University of Texas Medical Branch, Galveston, Texas.

8. From October 1981 to July 1987, I was Consultant to St. Mary's Hospital, Galveston, Texas.

9. From May 1983 to July 1987, I was Medical Director, Adult Special Care Unit (Rehabilitation), The University of Texas Medical Branch, Galveston, Texas.

10. From June 1983 to July 1987, I was Consultant to the Texas Institute for Rehabilitation and Research, Houston, Texas.

11. From June 1984 to July 1987, I was Director, Chronic Pain Unit, The University of Texas Medical Branch, Galveston, Texas.

12. From June 1985 to July 1987, I was Instructor for the American College of Surgeons, Advanced Trauma Life Support.

13. From June 1986 to July 1987, I was Medical Director, Neurosurgery Intensive Care Unit, The University of Texas Medical Branch, Galveston, Texas.

14. From July 1987 to the present, I am Clinical Associate Professor, The University of Texas Southwestern Medical Center, Dallas, Texas.

15. From July 1987 to the present, I have been in private practice as a Neurosurgeon at Neurosurgical Associates of Dallas, Dallas, Texas.

16. In 1992 I discovered that subcutaneous tissue conducted electricity in dermatomal fields to cause paresthesia. I discovered this by observing that an electric field applied to subcutaneous tissue caused paresthesia even though the electric field was applied to a region removed from major nerves. Dermatomal fields are areas on the skin innervated by select nerves. Paresthesia is a tingling sensation caused by nerve stimulation. Paresthesia is often used to mask or block pain.

17. Based on my observation of paragraph 16, in 1992 I formed the idea of treating pain by electrically stimulating the subcutaneous tissue near a nerve of interest. Specifically, in 1992 I formed the idea of treating superficial forehead pain by placing a lead in the subcutaneous tissue of the forehead.

18. Based on the idea I formed as described in paragraph 17, I first implanted a percutaneous lead subcutaneously in a patient's forehead for the treatment of superficial forehead pain in late 1992. I performed a first follow-up visit on this patient 10 days after the implant. Periodic follow-up on this patient continued for over a year. I subsequently implanted an additional three patients using substantially this technique over the next several years. In each such patient, I performed follow-up visits 10 days after the procedure and continued periodic follow-up visits with each patient to monitor the patients for over a year including some such patients who I have been monitoring for over seven years. I do not believe I have enough patients, data and long-term follow up to conclude that this technique is safe and effective over a long period of time.

19. From late 1992 to about 1993 I experimented with placing the leads subcutaneous in areas of the body to treat pain other than forehead pain as described above and occipital pain as described below. Specifically, I placed leads in the hernia area and over the scalp of patients to treat pain. After about 1993, I did not perform any more experiments using my percutaneous techniques other than to treat occipital pain as described below, placing electrodes in the foreheads of five patients to treat post-herpetic neuralgia, one patient to treat post craniotomy incisional neuroma pain, two patients to treat chronic medean nerve neuropothy and one patient to treat post hernia repair incisional pain.

20. I first implanted a lead for the treatment of pain caused by occipital nerves in March 1993. With this patient, I first implanted a paddle lead subcutaneously transversely across the patient's occipital nerve in the neck at about the C1 region. Placement of the paddle lead required me to surgically expose the patient's fascia above the C1 region and place the paddle lead thereon. Thereafter, the wound around the paddle lead was closed leaving the paddle lead subcutaneously placed.

21. Intra-operatively, I observed that the patient was not getting the desired pain relief from the paddle lead. Therefore, I removed the paddle lead. Although I did not know the optimal depth to place a percutaneous lead, I replaced the paddle lead with a percutaneous lead by placing the percutaneous lead on the fascia where the paddle lead had been. This lead appeared to produce the desired pain relief but, due to swelling and other complications of the surgery to place the paddle lead, the patient needed to recuperate from the surgery before the effectiveness of using a percutaneous lead in this manner could be evaluated.

22. After nine months, this patient asked to have the implant removed stating that he did not believe he was getting the pain relief he desired. I assented and removed the lead in December 1993. After I removed the lead, the patient immediately noticed that he had not appreciated the amount of pain relief the system had provided. Never the less, we agree that he would not have another implant for awhile so that the patient could assess the benefit of having the implanted system versus not having the system.

23. Approximately six weeks after the first implant was removed, the patient strongly requested that he receive another implant. I percutaneously and subcutaneously implanted another lead in the patient over the C1 region in January 1994. The patient used the system for approximately three years. At that time, the patient asked to have the system removed because his pain had resolved. I then removed the system in December of 1996.

24. Modifications to the technique to treat occipital pain originally performed in 1992 as described above in paragraphs 20 – 24 were made. These modifications included modifications in where and to what depth to implant the lead, how to anchor the lead to prevent migration, techniques to tunnel the lead extension from the lead to the implanted pulse generator (IPG) and the length of the lead and the corresponding location of the location of the connector that connects the lead to the IPG.

25. Specifically, the original 1993 implant to treat occipital pain was implanted at the back of the head to an uncertain depth. The technique was gradually modified over approximately

a two to three year period. During that time, I tried moving the implantation location to various locations from sub-occipital to the C2/C3 area. In about 1995, I determined that the optimum location for implantation to treat occipital pain is over the C1 vertebral segment.

26. Further, during the two to three year period mentioned in paragraph 25, I experimented with the depth that the percutaneous lead should be placed. I tried implantation depths of from into the muscular tissue of the deltoid muscles to above the fascia. Also in about 1995, I realized that the optimal depth of implantation to treat occipital pain is superficial, that is, above the fascia.

27. As I experimented with determining the optimal depth to implant a percutaneous lead to treat occipital pain, I realized that I needed to develop a technique for placing the percutaneous lead at desired depths at various locations from sub-occipital to the C2/C3 region. Since this area is in the neck and because the fascia of the neck, an area of interest for implantation, is curved, I needed to develop a technique for percutaneously implanting a lead into such a curved area. By about late 1993, I had created the technique of bending a Touhy needle to the approximate curvature of the subcutaneous tissue above C1 and then using this bent needle as an introducer to place the percutaneous lead.

28. Further, as I developed the technique to treat occipital pain by percutaneous implantation of a lead, I used a series of percutaneous leads to determine the optimal lead to perform the technique. The lead I used for my initial cases beginning in 1993 was a Resume™ lead. I progressed from using the Resume™ lead to using Pisces Quad™ leads to using Quad+™ leads, all of which are made and sold by Medtronic, Inc. of Minneapolis, Minnesota. Further, I progressed from using only a single lead to using two leads to treat bilateral occipital pain.

29. I also made other modifications to the technique used in the original 1993 implant to treat occipital pain. Initially, to anchor the percutaneous lead, I used the anchor supplied by the manufacturer with the lead. I eventually became aware that this anchor was not preventing the lead from migrating. Therefore, I developed a technique that I call the "Loop Technique" to prevent lead migration. The Loop Technique creates a subcutaneous pocket to receive a loop comprising the proximal end of the lead and the extension that connects the lead to the IPG. This technique took approximately two to three years to develop.

30. I have been experimenting with another anchoring technique for the last six to eight months. This technique involves using a knobby anchor held in contact with the tissue by medical grade silicone glue to prevent lead migration.

31. I also made modifications to the tunneling process. Tunneling is the process of moving the connecting wires under the skin from the implanted electrical stimulating device to the lead. Specifically, I originally used a rod with a blunt plastic tip to create the tunnel, both from the lead implant site to the subcutaneous pocket of the Loop Technique and from the subcutaneous pocket to the IPG. After experimenting with tunneling in the first year, I realized that using the blunt tip to create the tunnel from the lead implant site to the

subcutaneous pocket was not effective. Thereafter, I developed a technique using a tunneling tool with a sharp metal tip to create the tunnel between the lead implant site and the subcutaneous pocket.

32. In addition, I made modifications to the length of the lead and the corresponding location of the connector that connects the lead to the IPG. Initially, I used a relatively short lead. This resulted in the connector being located too high on the patient's neck which caused patient discomfort. I continued to modify the length of the lead in an attempt to move the connector to a more comfortable position. Since 1997, I have used a lead that was long enough to allow the connector to be placed at the abdomen. This is the technique I currently use in treating occipital pain by percutaneous stimulation.

33. I continued to follow the progress of patients implanted with leads to treat occipital pain from the initial implant until approximately two years after the implant in order to evaluate the long-term efficacy of the technique and identify problems.

34. On or about June or July 1998, the International Neuromodulation Society, 4th International Congress in Lucerne, Switzerland in September 1998 sent out a notice for potential presenters to the Congress to submit abstracts of their proposed presentations. As a result of this notice, I began thinking about topics that I could present to the Congress. In thinking about my technique to treat occipital pain, I began to determine whether I had enough patients with 6 six year follow-up data and approximately 70-80% efficacy to allow me to conclude that the technique to treat occipital pain was safe and effective over a long-term and not a short-term quirky effect.

35. The reason I needed long-term follow-up data is because almost any technique, including placebo techniques, has a short-term benefit. Therefore, it was important for me to observe the results of my technique for a long term. Further, because pain is subjective and measures to quantify pain are also subjective, it was important for me to have a large patient database in order to conclude that the technique was effective and not just an isolated event.

36. In the medical profession, the common measure for safety and efficacy is 25 – 30 patients in a 5-6 year study with a 2-year follow up for each patient. The reason for this large number of patients is to provide a sample sufficiently large to produce statistically valid results. By about June or July 1998, I concluded that my technique to treat occipital neuralgia was safe and effective, based on the 25- 30 patients I had implanted using my technique.

37. In response to the notice to submit abstracts from the Congress, I presented an abstract to the Congress in about July 1998. The abstract was accepted. As a result, in September 1998, I presented a lecture entitled "Peripheral Nerve Stimulation in the Treatment of Occipital Neuralgia" to the Congress. In this lecture, I described for the first time in public the details of my technique and expressed for the first time my belief that I had sufficient confidence, based on the number of patients implanted and the length of the follow-up, to conclude that my technique, as modified as described above, was safe and effective.

38. I have given lectures several times per year since 1993 on the subject of peripheral nerve stimulation generally. These lectures were given to neurosurgeons at national medical meetings. These lectures described non-percutaneous techniques for placing surgical leads in electrical contact with peripheral nerves. In these lectures, I also occasionally presented anecdotal descriptions of and comments on my percutaneous technique for treating occipital pain. When I discussed my percutaneous technique for treating occipital pain, I would publicly speculate on whether the technique would prove to be safe and effective for long-term treatment of occipital pain.

39. With respect to placing leads percutaneously at other locations to treat other peripheral nerve pain other than those mentioned above, prior to filing the instant patent application I have only discussed these ideas with my colleagues on a confidential basis.

40. To all patients that I applied my percutaneous technique, I informed them that the technique was being developed and that the technique was the application of an FDA approved device for an off-label use.

41. To all patients that I applied my percutaneous technique, I was paid my normal fee for performing the procedure and for the follow-up visits.

Further affiant sayeth not.

Richard L. Weiner

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